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APR 26 2002

This is in reply to the status letter received on April 24, 2002 in the application for patent term extension for U.S. Patent No. 5,532,221, filed January 15, 2002, based upon regulatory review of the product Gynecare Intergel. The status letter notes that 35 U.S.C. § 156(d)(2)(A)(ii) requires the United States Patent and Trademark Office (Office) to provide notice to the Secretary of Health and Human Services of the filing of the patent application within sixty days of filing of the application.

Although a copy of the application for patent term extension was forwarded to the Secretary on February 19, 2002 (note the attachment), the Office has not yet provided the notice required of the statute (the notice requires the Office to inform the Secretary that the patent claims a product subject to the Federal Food, Drug and Cosmetic Act, or a method of manufacturing or use of such a product, and a decision has not yet been made whether the patent contains such claims).

Consistent with the memorandum of understanding between the Office and the Food and Drug Administration (FDA), the Office is waiting for a reply from the Secretary before providing the notice. See 52 Fed. Reg. 17830 (May 12, 1987). Although this intermediate step of obtaining further information from the Secretary appears to have resulted in the Office missing the sixty day period, the delay is necessary because it enables the Office to better determine whether the application is eligible for patent term extension before FDA determines the regulatory review period, and holds any required due diligence hearings. Without this information, the Office may make erroneous decisions of eligibility, and lead to the FDA having to make regulatory review determinations and hold hearings in applications that are not eligible for patent term extension.

Once the Office receives the requested information from the Secretary, the Office will provide the required notice and, shortly thereafter, the Secretary will make the determination of the length of the regulatory review period.

Inquiries regarding this communication should be directed to the undersigned at (703) 306-3159 (telephone) or (703)308-6916 (facsimile).

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

Enclosure: Letter dated February 19, 2002

Memorandum of Understanding Between the Patent and Trademark Office and the
Food and Drug Administration, 52 Fed. Reg. 17830 (May 12, 1987).

cc: David T. Read
Acting Director Health Assessment Policy Staff, CDER
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